

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

**This Document Relates to the TPP Trial
Subclasses**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

**ZHP DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF
MOTIONS IN LIMINE¹**

¹ These Motions in Limine concern the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"), specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC, as class representative of TPP Breach of Express Warranty subclass b, TPP Breach of Implied Warranty subclass d, TPP Fraud subclass c, and TPP State Consumer Protection Laws subclass a, against the TPP Trial Defendants. (ECF [2343](#) at 1-2.)

Defendants Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai U.S., Inc.; Princeton Pharmaceutical Inc.; and Solco Healthcare U.S., LLC (collectively, the “ZHP Defendants”), by and through their undersigned counsel, respectfully move to exclude certain evidence from trial of this matter.

1. COMMUNICATIONS AMONG ZHP EMPLOYEES INVOLVING IRRELEVANT REGULATORY ISSUES

The ZHP Defendants anticipate that plaintiffs will seek to introduce evidence related to memorandums or email communications in which Huahai U.S. employee Remonda Gergis criticized the compliance environment at ZHP. For example, in a memorandum dated January 19, 2010, two years before ZHP adopted the TEA with quenching process and more than three years before the adoption of the Zinc Chloride process, Ms. Gergis complained about various conditions at an unidentified ZHP workshop, including, among other things, that “the calibration/maintenance labels on the major equipments [sic] were expired” and “[c]onnecting hoses were neither dedicated nor carry any identification.” (PRINSTON00463786 at -3786 (Ex. 1 to Cert. of Jessica Davidson (“Davidson Cert.”)).) She opined that these issues meant that the workshop was “an operation that is out of control.” (*Id.*) She further suggested that the QA personnel with whom she had interacted did not “fully understand their responsibilities.” (*Id.* at -3787.)

This memorandum is irrelevant because there is no evidence that the workshop in question was one where valsartan API was manufactured using the

processes at issue, and even if it had been, Ms. Gergis's comments were principally focused on missing labels and what she perceived as a lack of expertise on the part of certain unidentified staff members. There is no allegation in this case related to missing labels; nor is there any evidence that any of the staff members discussed by Ms. Gergis played any role in manufacturing of valsartan API or finished dose valsartan.

Likewise, in a 2015 email chain, Ms. Gergis faulted ZHP's quality control processes for allowing a number of valsartan finished doses to be mis-stamped, an error she believed had been discovered too late in the process. (*See generally* PRINSTON00170081 (Davidson Cert. Ex. 2).) Among other things, Ms. Gergis suggested that the fact that the mistake had been discovered so late in the process—during packaging—showed that “on-line testing is not done timely, whether for negligence or insufficient inspectors.” (*Id.* at -0083.) Once again, none of her comments relates to ZHP's adoption and use of the Zinc Chloride and TEA with quenching processes to manufacture valsartan API.

Ms. Gergis's criticisms, which centered on labeling and other issues unrelated to this matter, should be excluded under both Fed. R. Evid. 401 and 403. For one thing, the evidence is utterly irrelevant to the central questions in this lawsuit, which relate to alleged impurities in valsartan. In addition, this evidence would be unduly prejudicial because Ms. Gergis used very strong language to criticize ZHP

operations and would therefore inflame the passions of jurors. For both of these reasons, the evidence should be excluded.

2. EVIDENCE OR ARGUMENT REGARDING ZHP'S DISCARDING OF VALSARTAN BATCHES C5191-17-023/024

Plaintiffs have indicated that they intend to introduce evidence and/or argument at trial that ZHP discarded certain batches of valsartan API in 2017. Such evidence or argument should be barred because: (1) it is irrelevant; (2) any possible probative value would be vastly outweighed by the danger of unfair prejudice; and (3) its admission would lead to an unnecessary and time-consuming side show regarding the reason why the batches were discarded.

On August 2, 2017, ZHP opened a deviation investigation regarding valsartan API batches C5191-17-023/024 after a workshop manager notified quality Control that a single unknown impurity in the batches rendered them out of specification ("OOS"). (ZHP00165283 at -5283 (Davidson Cert. Ex. 3).) Following an investigation aimed at identifying the root cause of the OOS impurity, ZHP issued a deviation investigation report stating that "[b]y reviewing historical deviation/OOS/complaint, no similar issue occurred" in other batches, and "[i]t was suspected that this OOS was probably due to occasional fluctuation in manufacturing process." (*Id.* at -5288.) The batches at issue were then discarded on August 22, 2017 in an abundance of caution to ensure that they did not reach consumers. (*See* Dep. of Jucai Ge 183:17-19, Apr. 28, 2021 (Davidson Cert. Ex. 4) ("Based on the risk, we

decided to destroy the -- both batches in order to prevent them from entering into the market.”).) This was almost a year before ZHP first learned that its valsartan API contained NDMA (*see* Dep. of Jucai Ge 279:21-280:7, Apr. 29, 2021 (Davidson Cert. Ex. 5) (“I did not have any understanding of the NDMA impurity until June 2018 when Novartis provided us the feedback.”); ZHP01344159 (Davidson Cert. Ex. 6) (noting a customer complaint regarding NDMA on June 6, 2018)) and more than a year before the first lawsuit regarding valsartan was filed. As a result, there is no evidence that ZHP had a duty to retain these OOS samples of valsartan API in August 2017, and certainly no reason to suggest that ZHP acted improperly in discarding valsartan batches C5191-17-023/024.

Nevertheless, the ZHP Defendants anticipate that plaintiffs will attempt to reference the destruction of these batches at trial. Any such reference would be irrelevant to the central issues in this trial and would result in significant and unfair prejudice to the ZHP Defendants. Importantly, the ZHP Defendants do not seek to preclude plaintiffs from introducing evidence regarding the identification of an OOS impurity in batches C5191-17-023/024, or the resulting deviation investigation, even though there is no reason to believe those impurities had anything to do with NDMA or NDEA. Rather, the ZHP Defendants only seek to preclude evidence regarding the destruction of valsartan batches C5191-17-023/024 after the conclusion of that investigation. This is because the only feasible purpose for introducing such

evidence would be to unfairly prejudice the jury by insinuating that ZHP did something wrong in discarding valsartan batches or was attempting to hide the fact that these batches contained NDMA or NDEA. There is no evidence to support either theory.

In addition, evidence regarding the disposal of batches of C5191-17-023/024 would create substantial confusion and delay. If plaintiffs are allowed to introduce evidence that valsartan batches were discarded, it would require the presentation of testimony about irrelevant legal and factual issues, including whether ZHP had a duty to preserve these batches (which it did not), and the specific reasons why those batches were not retained. Such a “trial within a trial” would distract and confuse jurors in an already complicated trial. *See Brookshire Bros., Ltd. v. Aldridge*, 438 S.W.3d 9, 26 (Tex. 2014) (prohibiting mention of the potential destruction of evidence because it has a “tendency . . . to skew the focus of the trial from the merits to the conduct of the . . . party” that discarded the materials and “raises a significant risk of both prejudice and confusion of the issues”); *see also Thompson v. Glenmede Trust Co.*, No. CIV. A. 92-5233, 1996 WL 529693, at *2 (E.D. Pa. Sept. 17, 1996) (excluding evidence related to discovery disputes due to risk that “the jury may . . . be misled by the irrelevant side issues of the discovery process,” “[r]ather than focus on the issues in the case”).

3. REFERENCES TO EMAIL CORRESPONDENCE BETWEEN CHARLES WANG AND JIM MCDONALD

The Court should exclude all email correspondence between two non-ZHP employees, Charles Wang and Jim McDonald (*see, e.g.*, CHARLESWANG000447 (Davidson Cert. Ex. 7)), because such evidence is quintessential hearsay that does not satisfy any applicable exception. *See, e.g., Sanofi v. Lupin Atl. Holdings S.A.*, 282 F. Supp. 3d 818, 840 (D. Del. 2017) (statements made by non-employees were inadmissible hearsay); *Mitchell v. Sun Drilling Prods., Inc.*, No. 95-1487, 1996 WL 411613, at *2 (E.D. La. July 22, 1996) (“[D]ocuments . . . written by non-employees . . . constitute hearsay.”).

The ZHP Defendants anticipate that plaintiffs may argue that Wang is an agent of ZHP, rendering his statements non-hearsay. This contention has no merit. Rule 801(d)(2)(D) provides that a statement is not hearsay if it “is offered against an opposing party” and “was made by the party’s **agent or employee** on a matter within the scope of that relationship.” Fed. R. Evid. 801(d)(2)(D) (emphasis added). The onus is on the **proffering party** to establish that the statement in question was made by an agent or employee of the opposing party. *See Lippay v. Christos*, 996 F.2d 1490, 1497 (3d Cir. 1993) (“As the proponent of the evidence, [the plaintiff] had the burden to demonstrate that [the declarant] made this statement within the scope of an agency relationship with [the defendant].”). Third Circuit courts have made it clear that an agency relationship is “established only where the party-opponent

personally ‘directed [the declarant’s] work on a continuing basis.’” *Id.* at 1498 (citation omitted). Where there is a lack of “continuous supervisory control” over the declarant, “an agency relationship for the purposes of Rule 801(d)(2)(D)” does not exist. *Id.* at 1499. Consistent with this rule, courts have repeatedly recognized that declarants who perform “independent assessment[s]” or served merely as “independent contractors” are not “agents” for the purposes of Rule 801(d)(2)(D). *See, e.g., Conduis v. Howard Sav. Bank*, 986 F. Supp. 914, 916-17 (D.N.J. 1997) (declarant who “was a forensic bank examiner hired to ‘provide an independent assessment’ of [defendants]’s procedures” was not an agent of the defendant because the defendant “did not control the method in which [the declarant] conducted its assessment”).²

Such is the case here. The evidence shows that Min Li considered Wang to be a personal friend and “consultant . . . of ZHP.” (Dep. of Min Li, Ph.D. (“4/22/21 Min Li Dep.”) 531:6-20, 554:10-18, Apr. 22, 2021 (ECF [2569-4](#) at Ex. 51).) In this limited consultant role, Wang conducted independent safety assessment reports for

² *See also, e.g., Sanofi*, 282 F. Supp. 3d at 840 (holding the proffering party did not show “that speaking authority was bestowed expressly or implicitly upon” the “clinical trial investigators” because “[t]he evidence suggests that [the investigators] maintained a good amount of independence from [the opposing party]”); *Merrick v. Farmers Ins. Grp.*, 892 F.2d 1434, 1440 (9th Cir. 1990) (statements were inadmissible hearsay where proponent “did not establish that the insurance agents and the district manager were ‘agents’ of Farmers as opposed to independent contractors”).

ZHP from time to time in exchange for an agreed-upon fee. (*See, e.g.*, ZHP00675949 (Davidson Cert. Ex. 8); 4/22/21 Min Li Dep. 551:15-552:10 (Li explaining he contacted Wang “to evaluate” the NDMA notice from a “toxicological perspective” due to his toxicology expertise).) Wang, however, was not an employee of ZHP and ZHP did not exercise direct control over Wang’s reports or how he worked. (*See, e.g.*, 4/22/21 Min Li Dep. 630:14-631:12, 647:9-23.) In short, Wang’s role providing limited “consulting” or “expert” services to ZHP on occasion for a fee does not render him an “agent” of ZHP, and his statements to McDonald are thus inadmissible hearsay. *Lippay*, 996 F.2d at 1499 (noting that declarant’s “tenuous” work with opposing party and “occasional payments to” the declarant evidenced that the declarant “functioned as a sort of independent contractor” for which Rule 801(d)(2)(D) did not apply).³

³ Even if Wang were found to somehow be an agent of ZHP, it is indisputable that McDonald has no agency or employee relationship with ZHP. Further, it is blackletter law that “email chains” or “email strings” are not “categorically admissible,” but rather, “[e]ach [e]mail [m]erits [i]ndividual [c]onsideration.” *In re Oil Spill by Oil Rig “Deepwater Horizon” in Gulf of Mex., on Apr. 20, 2010*, MDL No. 2179, 2012 WL 85447, at *2 (E.D. La. Jan. 11, 2012); *see also Merrill v. Pathway Leasing LLC*, No. 16-cv-02242-KLM, 2018 WL 2214471, at *6 (D. Colo. May 14, 2018) (holding that “the portions of those emails written by [d]efendant Matthew Harris are admissions by a party opponent” and thus admissible, but excluding portions of email chains “not written by” the defendant). As such, and at a minimum, the hearsay statements made by non-party McDonald should be stricken.

WHEREFORE, the ZHP Defendants respectfully request that the Court issue an order excluding the evidence described herein from trial.

Dated: February 16, 2024

Respectfully submitted,

By: /s/ Jessica Davidson
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 16, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson
Jessica Davidson